510(k) SUMMARY

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

Submitted by

INNERCOOL *therapies*, Inc.
3931 Sorrento Valley Boulevard
San Diego, California 92121
Telephone: (858) 713-9507
Contact: Steve Reitzler, Vice President, Regulatory Affairs & Quality Assurance
Date Prepared: July 19, 2002 (Revised: January 17, 2003)

Device Name

Trade or Proprietary Name:	***Celsius Control™ System***
Common or Usual Name:	Thermal Regulating System
Classification Name:	Thermal Regulating System

Predicate Devices

The subject device is substantially equivalent, in whole or in part, to predicate devices manufactured by Medivance, Inc. (K002577), MTRE Advanced Technology, Ltd. (K003349), Seabrook Medical Systems (K902756), Cincinnati Sub-Zero Products, Inc. (K811743), Gaymar Industries, Inc. (K912051), and Radiant Medical (K012512).

Device Description

The subject device is a thermal regulating system consisting of three (3) parts:

- an endovascular catheter having a heat exchange element at the distal end, through which a thermal transfer fluid is circulated to cool or warm the blood, and which is available in various diameters from 9 french to 14 french;
- a console containing refrigeration/heating elements, a heat exchanger to cool and warm the circulating fluid, a pump to circulate that fluid, and controls and software necessary to operate the system; and

- a sterile tubing set to connect the console to the catheter, and through which the heat transfer fluid is circulated to and from the catheter.

Two (2) models of the System are available: One which uses conventional, off-the-shelf thermistor probes such as esophageal probes, to monitor patient temperature and control System operation, and one that uses a thermistor integral to the catheter.

Blood contact components of the device have been demonstrated biocompatible through testing in accordance with EN ISO 10993. The System meets applicable standards for electrical safety and electromagnetic compatibility, including EN 60601-1-2 and EN 61003-3-3.

Intended Use

The Celsius Control™ System *is a thermal regulating device intended to induce, maintain, and reverse mild hypothermia in neurosurgical patients in surgery and in recovery/intensive care.*

Comparison to Predicate Devices

The subject device has the same, or equivalent, indications for use as do other thermal regulating systems cleared for commercial distribution in the U.S.;

The subject device has the same or equivalent design characteristics as other thermal regulating systems cleared for commercial distribution in the U.S.;

The subject device is composed of biocompatible materials meeting the requirements of ISO 10993-1, as are other devices cleared for commercial distribution in the U.S.;

The subject device has been shown through non-clinical and clinical studies to have equivalent performance in inducing and reversing hypothermia, and in maintaining normothermia, as other thermal regulating systems commercially available in the U.S.

Summary of Non-Clinical Tests

Both *in vitro* and *in vivo* studies demonstrate the ability of the subject device to quickly cool and rewarm a subject to user-designated target temperatures, to accurately control subject temperature at a user-designated target temperature – whether hypothermic or normothermic – and to do so without presenting measurable safety hazards.

Summary of Clinical Tests

Clinical studies have established that the ***Celsius Control™ System*** can rapidly cool a patient to a physician-designated hypothermic target temperature, can maintain that temperature within narrow tolerances, and can return the patient to normothermia as effectively as can predicate thermal regulating systems. Clinical studies have also demonstrated that the incidence of adverse events associated with use of the ***Celsius Control™ System*** is comparable to that associated with other comparable medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 7 2003

INNERCOOL Therapies, Inc.
Stephen Reitzler
Vice President, Regulatory Affairs and Quality Assurance
3931 Sorrento Valley Boulevard
San Diego, California 92121

Re: K022366
Trade/Device Name: INNERCOOL Therapies, Inc., Celsius Control™ System
Regulation Number: 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: NCX
Dated: November 5, 2002
Received: November 7, 2002

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 DRAFT LABELING

5.1 Indications for Use

510(k) Number (if known): K022366

Device Name: INNERCOOL *therapies*, Inc., ***Celsius Control™ System***

Indications for Use:

The Celsius Control™ System *is a thermal regulating system intended to induce, maintain and reverse mild hypothermia in neurosurgical patients in surgery and in recovery/intensive care.*

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K022366

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)